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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,758	09/29/2006	Yoshihiro Nomura	296946US0PCT	5292

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1656

NOTIFICATION DATE	DELIVERY MODE
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04/15/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/594,758	<b>Applicant(s)</b> NOMURA ET AL.	
	<b>Examiner</b> Marsha M. Tsay	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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This Office action is in response to Applicants' remarks received December 31, 2009.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claim 6 is canceled. Claims 1-5, 7-29 is currently under examination.

Priority: The request for priority to JAPAN 2004-107286, filed March 31, 2004, is acknowledged. A certified copy of the foreign priority document has been filed in this case on September 29, 2006, and is in a non-English language.

The indicated allowability of claims 8 and 22 are withdrawn upon further consideration of the Schrooyen et al. reference (US 7169896). Rejections based on the reference are below.

### **Objections and Rejections**

Claims 26, 28 are objected to because of the following informalities: in claims 26, 28, the term "sililated" should be corrected to "silylated". Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 27, 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 29 recite keratin which is not chemically modified. It is unclear how the keratin is not chemically modified since the keratin has been hydrolyzed and neutralized in solution, which would result in the modification of the keratin structure. Further clarification is requested.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrooyen et al. (US 7169896) in view of Mullner et al. (WO 0236801 abstract; previously cited). For examination purposes, claim 1 has been interpreted as: a method for producing solubilized keratin comprising (a) hydrolyzing a keratin raw material that has a water content ranging from 20 to 80% by weight, in an alkali solution; (b) neutralizing the hydrolyzate liquid containing solubilized keratin; and (c) extracting a solubilized keratin from the supernatant, wherein said keratin has an average molecular weight of 8,000 to 13,000 Da.

In col. 15, lines 50-67, Schrooyen et al. disclose a process for producing partially modified and partially hydrolyzed keratin comprising the steps of (a) solubilizing keratin in an aqueous solution containing a reducing agent and at an alkaline pH between 10 and 13.5, at a

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temperature of at least 40° C; (b) partially modifying the –SH groups of the solubilized keratin (i.e. in this instance, alkylation); (c) and obtaining solubilized keratin that has a molecular weight (MW) between 1 kDa and 10.4 kDa. Regarding the modification step of (b), Schrooyen et al. further disclose that modification of the solubilized keratin is not limited to alkylation, but can also include treating said keratin with hydrogen peroxide, chloroacetic acid, etc. (col. 7 lines 1-10). Schrooyen et al. further disclose that the aqueous alkaline solution, used in the solubilization step of (a), can contain an alkali metal sulphide or ammonium sulphide between 0.05 M and 1.0 M, or a combination of 2-mercaptoethanol and sodium hydroxide (col. 4 lines 41-47). The solubilization step of (a) can take between 10 minutes to 24 hours (col. 4 lines 60-65). The keratin starting material can be poultry feathers (abstract). Schrooyen et al. also disclose that the keratin material can be pre-treated prior to the hydrolysis reaction (col. 8 lines 58-67) but do not teach a hydrous state of 20 to 80%.

Mullner et al. disclose keratin protein hydrolysates obtained from keratinous waste (i.e. wool, feathers, hooves, etc.) are suitable for use in cosmetic compositions (p. 3). Mullner et al. disclose that the substrate is a natural proteinaceous product preferably with a water content of 5-99 weight %, especially a substrate containing keratin (p. 4). The final keratin protein product contains substantially no toxic constituents (p. 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Schrooyen et al. by substituting the keratin material (having a water content in the range of 5-99 wt %) of Mullner et al. for the keratin starting material used in Schrooyen et al. for a process of producing a solubilized keratin comprising a solubilization step in an alkali solution, a treatment step with hydrogen peroxide or acid, and obtaining a

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solubilized keratin having a MW between 1 kDa and 10.4 kDa, as disclosed by Schrooyen et al. (claims 1-5, 7-29). The motivation to do so is given by Mullner et al., which teach that using a keratinous substrate having a water content in the range of 5-99 weight % in a protein hydrolysis process can eliminate toxic constituents in the final keratin protein product, therefore, it would be reasonable for one of ordinary skill to want to improve upon the process of Schrooyen et al. by using a starting material that will reduce the toxicity of the end product.

Regarding step (b), it would be reasonable for one of ordinary skill to know that the modification step of Schrooyen et al. would be functionally equivalent to the instant neutralization step since Schrooyen et al. disclose that said modification step is performed after a hydrolysis step in an alkali solution and said modification step can be performed using the same agents as the instant invention (i.e. hydrogen peroxide or acid).

Regarding the use of a reducing agent in the alkali solution of Schrooyen et al., it should be noted that the use of open claim language "comprising" allows for the inclusion of additional components, therefore, since Schrooyen et al. disclose the instant active steps and a keratin product that meets the instant MW, the keratin product of Schrooyen et al. is believed to be functionally equivalent to the instant keratin product. However, inclusion of the reducing agent in the alkali solution of Schrooyen et al. would still be functionally equivalent to the instant hydrolyzing step in an alkali solution because in both instances, the disulfide bonds of the keratin will be cleaved.

Regarding the limitations of claims 26 and 28, Schrooyen et al. disclose ammonium sulphide can be used in the alkali solution (col. 4 lines 41-45) and would meet the scope of an ammonium derivative of a keratin hydrosylate.

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Regarding the limitations of claims 27 and 29, the keratin of Schrooyen et al. would be chemically unmodified if hydrogen peroxide is used in the modification step since it would take place of the alkylation step.

Regarding the product claims of claims 8, 9, 19, the keratin product of Schrooyen et al. would be functionally equivalent to the instant keratin product because Schrooyen et al. disclose variations of the instant active steps (i.e. hydrolyzing and neutralizing steps that use the same solutions as the instant invention) to obtain a keratin product that meets the scope of the instant MW range.

In their remarks, Applicants assert (1) there is simply no recognition in Schrooyen et al. that selecting a raw keratin raw material having a water content of 20-80% provides any benefit. (2) Schrooyen et al. involves alkaline extraction, it describes a method for making a significantly different chemically-modified keratin product (one that is reduced and alkylated) that has different physical properties and which is made by a method requiring reduction of disulfide bonds in keratin raw material and the subsequent modification (e.g., alkylation) of the sulfhydryl groups produced by reduction. Thus, Schrooyen et al. do not disclose “extracting a solubilized keratin from the supernatant that has an average MW of 8,000 to 13,000 Da.” Applicants’ arguments have been fully considered but they are not persuasive.

(1) Response: The deficiency of Schrooyen et al. to teach a keratin starting material having a water content ranging from 20 to 80% by weight is remedied by the Mullner et al. reference.

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(2) Response: The reducing agent in the alkali solution of Schrooyen et al. will cleave the disulfide bonds of the keratin protein. This is the same reaction that occurs in the instant hydrolyzation of keratin in an alkali solution because the disulfide bonds of the keratin protein will be cleaved. Therefore, both the keratin of Schrooyen et al. and the instant keratin have the same properties.

Regarding the subsequent modification (i.e. alkylation), this is explained above in the 103(a) rejection. Schrooyen et al. disclose that the subsequent modification can be performed with hydrogen peroxide or acid, which is functionally equivalent to the instant neutralization step. Therefore, when treated with hydrogen peroxide, the keratin of Schrooyen et al. would again have the same properties as the instant keratin.

Further, Schrooyen et al. further disclose that the end keratin product has a MW between 1 kDa and 10.4 kDa, which is within the range of the MW recited in instant claim 1.

For at least these reasons, the claims remain rejected under 103(a).

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after



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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 9, 2010

M. Tsay  
Art Unit 1656

/Manjunath N. Rao /  
Supervisory Patent Examiner, Art Unit 1656